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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,994	04/19/2004	Cynthia T. Clague	P-21018.00	3521

27581 7590 04/02/2007

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,994	CLAGUE ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-43 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/9/06, 2/13/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The disclosure is objected to because of the following informalities: On page 1 of the specification in the section entitled "Reference to Related Application", Applicants are requested to provide the serial number of the commonly assigned U.S. provisional application referred to.

Appropriate correction is required.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-2, 21-23 and 41-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 21, 42, 44-46, 71, 78-79 and 85-86 of copending Application No. 10/892,000. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims recites a system, a test cartridge and a method for performing a coagulation time test on a biologic test sample that comprises a test cartridge formed of a cartridge housing having at least one test chamber therein into which a test sample is deposited, an agitator mounted at a pivot point in the test chamber having an agitator vane adapted to be swept about the pivot point through the test sample, a test instrument having a receptacle for supporting the test cartridge therein, a sweeping means in the test instrument for sweeping the agitator vane about the test chamber pivot point through the test sample, detecting means in the test instrument for detecting a reduction of sweeping movement of the agitator vane, and timing means in the test instrument for timing a coagulation test time elapsed from the commencement of sweeping of the agitator vane until detection of the reduction of the sweeping movement.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Nippoldt et al (US 2005/0255601, submitted in the Information Disclosure Statement filed on February 9, 2006).

Nippoldt et al teach of a blood coagulation test cartridge, system and method. In the embodiment depicted in Figure 6, the test cartridge 50 comprises a cartridge housing 52 having a substantially prismatic shape with first and second major sides 54 and 56, and a minor sidewall 58 extending between the first and second major sides 54, 56. The cartridge housing 52 is formed of a transparent and relatively rigid material. The cartridge contains a blood receptacle or test chamber 82 therein that has a centrally disposed axle or pivot point 84 extending from the closed side 56. An impeller or agitator 90 is supported along the length of the axle 84 for rotation about the axle 84. The impeller 90 can be formed as a propeller, opposed fins, opposed paddles, or opposed blades with perforations therein. See Figure 6 in Nippoldt et al that depicts the agitator 90 as having opposed vane leaflets having curved concave or convex sides, notched sides, slotted sides or as a window having a mesh covering. Movement of the agitator 90 causes a blood sample in the test chamber 82 and reagents therein to be mixed together. The impeller is preferably formed of a metal that is magnetizable or responds to a magnetic field. A motor driven or hand driven magnet can be applied in proximity to the second surface 56 of the cartridge in axial alignment with the axle 84 and rotated. The rotating magnetic field that is produced envelops the agitator 90 and causes it to rotate about the axle 84, whereby the agitator 90 mixes the blood deposited into the chamber 82. The blood chamber can be coated with a reagent that serves to initiate coagulation in a blood sample such as kaolin, celite, glass particles, thrombin or thromboplastin so that coagulation tests such as thrombin time, PT, aPTT and ACT can be performed. See paragraphs 0041, 0044 and 0047 in Nippoldt et al. It is noted that the

"whereby" clause in instant claim 21 has no patentable weight since claim 21 is directed towards an apparatus, and the "whereby" clause in claim 21 is directed to an intended use of the apparatus, which the apparatus disclosed by Nippoldt et al would also be capable of performing since the structure of the device taught by Nippoldt et al is the same as the structure recited in instant claim 21.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 22-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippoldt et al. For a teaching of Nippoldt et al, see previous paragraphs in this Office action.

Nippoldt et al fail to teach that the test chamber in the cartridge housing is enclosed, and fail to teach of each of the different shapes of the agitator vane leaflets as recited in instant claims 22-40. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to enclose the test chamber in the cartridge taught by Nippoldt et al so as to completely enclose the blood sample therein so that the outside environment is not

contaminated by the blood sample. It also would have been obvious to one of ordinary skill in the art to change the shape of the agitator vane leaflets taught by Nippoldt et al to the various different shapes recited in claims 22-40 since shape is a result effective parameter that can be experimentally altered to optimize mixing of a blood sample and reagents in the test chamber, and the change in shape of an object with no unexpected results is an obvious design choice. See In re Dailey et al, 149 USPQ 47.

10. Claims 1-3, 6, 21-23, 26 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mpock et al (US 2003/0180824) in view of Bote Bote (WO 03/087817, English language equivalent is EP 1,503,211, both submitted in the IDS filed on February 13, 2006) and Chow (WO 02/063273, also submitted in the IDS filed on February 13, 2006).

Mpock et al teach of a system and test cartridge for performing blood coagulation assays. The cartridge 14 is intended to be inserted into a test instrument 12. Sensor and timing functions are present within the test instrument 12 to determine the clotting time of a blood sample applied to the cartridge 14. Cartridge 14 is made of a light transmitting plastic or another material that has good clarity. Cartridge 14 includes a reaction chamber 20, a sample receiving chamber 22 and an overflow chamber 24 formed into the body of the cartridge 14. A sample of blood is placed into the receiving chamber 22 where it then flows through a filling channel into the reaction chamber 20. The reaction chamber 20 can have a coagulation initiator such as thromboplastin, kaolin or diatomaceous earth therein. The reaction chamber 20 contains a pivot point 41 therein having an agitator 40 mounted thereon. The agitator 40 contains plural moveable members 42 in the shape of a paddle wheel. When the moveable members 42 are rotated about the pivot point 41, the members 42 serve to stir/mix the contents of the reaction

chamber 20. The moveable members 42 may each have a hooked or pointed or curved end. When the cartridge 14 is received in the receptacle of the test instrument 12, an actuator in the test instrument causes the central rotatable pivot point 41 to rotate, thus sequentially rotating moveable members 42 through the reaction chamber 20. A blood clot will form in the reaction chamber 20, and the clot will be lifted out of the chamber 20 when it becomes entangled on one or more of the moveable members 42. A sensor in the instrument 12 detects the presence of the clot, and a timer in the instrument 12 measures the interval of time between when the blood sample is received into the reaction chamber 20 and when the blood clot forms. The moveable members 42 may rotate one way in a circular path through the reaction chamber 20 (i.e. through 360 degrees), or they may be moved back and forth in an arcuate path (i.e. through less than 360 degrees, similar to a pendulum). A cover 31 is positioned over the reaction chamber 20 so as to enclose the chamber. Sensor 50 in the instrument 12 is an optical sensor that includes an eye 52 this is positioned to receive light from a light source 54. Eye 52 and sensor 54 detect the presence of a blood clot by detecting a change in the light passing between light source 54 and eye 52. Light passes directly through the body of the cartridge and through the reaction chamber 20 in order to detect a blood clot while still located in the reaction chamber 20. See Figures 1-6 and paragraphs 0062-0077 in Mpock et al. Mpock et al fail to teach that the sensor in the test instrument serves to sense when a reduction in the movement of the agitator 40 occurs, and that the timer serves to measure the time elapsed from the commencement of the movement of the agitator 40 until the movement is reduced by the formation of a blood clot.

Bote Bote teaches of a device and method for measuring coagulation of a blood sample. The device comprises a dish 3 into which a blood sample is placed. The blood sample flows

from the dish 3 into a conduit 4 having a blood coagulation reagent therein. The mixture of the blood sample and the reagent is ejected into a gap located between a cup 1 and a rotor 2. The rotor is caused to move by centrifugal force, which causes the blood sample and reagent to mix. A speed sensor 7 serves to measure the speed decrease of the rotor 2 caused by a clot formation 15. Due to the rotation of the rotor 2, the blood sample and reagent are mixed, and after a certain period of time, a clot 15 forms, causing an increase of mechanical friction between the rotor 2 and the cup 1 detectable due to its effect on the speed and on the torque of the rotor 2. The time elapsed between the start of the process and the moment in which the friction increase occurs causing a reduction in the movement of the rotor 2 is the coagulation time of the blood sample. See figure 1 and columns 2 and 3 in the English language equivalent EP 1,503,211.

Based on a combination of Mpock et al and Bote Bote, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to detect when blood coagulation occurs using the test cartridge and instrument taught by Mpock et al by detecting when a reduction in the movement of the agitator 40 occurs and by measuring the time elapsed from the commencement of the movement of the agitator 40 until the movement is reduced by the formation of a blood clot since the agitator 40 disclosed by Mpock et al will inherently reduce its speed of movement in the blood sample as a result of a blood clot forming in the sample, and Bote Bote teaches that one effective way in which to measure the time of blood coagulation in a sample being mixed or stirred with an agitator-type device is to detect the time at which the speed of the agitator in the sample is reduced.

Mpock et al also fail to teach that the test chamber 20 is cylindrical, that the pivot point 41 is disposed substantially in alignment with the axis of the cylindrical test chamber, and that

the moveable members 42 on the agitator 40 extend from the pivot point substantially across the test chamber radius.

Chow teaches of a device 30 for mixing a blood sample and causing turbulent shear therein. The device 30 includes a cylindrical rotor 32 retained in a housing forming a sample chamber 34. A top plate 36 comprises the upper portion of the housing. The cylindrical rotor has a non-uniform curvature on each side 33. The non-uniform curvature of the sides provides turbulent flow with multiple acceleration and deceleration zones inside the sample chamber. The rotor 32 is suspended between the top plate 36 and the wall 35 of the chamber 34 such that the rotor rotates freely along the center axis 38 of the device 30. The chamber 34 is transparent for easy viewing of the blood sample therein. The rotor 32 has one or more arms 40 for mixing a blood sample. One or more of the arms contain magnetizable material. As a result, the inner surface 31 of the rotor facing the bottom of the housing 34 is metalized such that the rotor can be driven by a radial magnetic field. Sources of a magnetic field include a permanent magnet or electromagnet mounted on a rotating device in close proximity to the external bottom surface 49 of the sample container 34. See figures 1-5 and pages 9-10 in Chow.

Based upon the combination of Mpock et al and Chow, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the pivot point 41 in the test chamber taught by Mpock et al in alignment with the cylindrical axis of the test chamber so that the moveable members 42 on the agitator 40 extend from the pivot point across the test chamber radius, similar to the configuration of the rotor in the test chamber disclosed by Chow, since Chow teaches that a rotor having multiple agitator vanes thereon that are situated in alignment with the cylindrical axis of the test chamber serve to effectively and efficiently mix a

blood sample, thereby causing turbulent flow therein that initiates blood coagulation, which is equivalent in function to the orientation of the moveable members 42 in the test chamber taught by Mpock et al.

11. Claims 4-5, 7-20, 24-25 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mpock et al in view of Bote Bote and Chow as applied to claims 1-3, 6, 21-23, 26 and 41-43 above, and further in view of Nippoldt et al. For a teaching of Mpock et al, Bote Bote and Chow, see previous paragraphs in this Office action.

Mpock et al fail to of each of the different shapes of the agitator vane leaflets as recited in instant claims 4-5, 7-20, 24-25 and 27-40. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to change the shape of the agitator vane leaflets taught by Mpock et al to the various different shapes recited in claims 4-5, 7-20, 24-25 and 27-40 since Nippoldt et al disclose that some of these shapes are very effective at mixing a blood sample and a reagent in a test chamber on a cartridge, shape is a result effective parameter that can be experimentally altered to optimize mixing of a blood sample and reagents in a test chamber, and the change in shape of an object with no unexpected results is an obvious design choice. See In re Dailey et al, 149 USPQ 47.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Braun, Sr. et al who teach of a method and device for measuring viscosity changes in fluids; and SU 1130306 that teaches of a container having an impeller with blades therein for mixing a blood sample.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

March 28, 2007

Maureen M. Wallenhorst
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